UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JOSEPH PAYE,	)	
	)	
Plaintiff,	)	
	)	**Civil Action No.**
v.	)	**22-10005-FDS**
	)	
ATRIUM MEDICAL CORPORATION; GETINGE AB; and MAQUET CARDIOVASCULAR US SALES, LLC,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER ON
DEFENDANTS' MOTION TO DISMISS

SAYLOR, C.J.

This is a lawsuit against three medical-device companies. Jurisdiction is based on diversity of citizenship.

Plaintiff Joseph Paye alleges that defendants Getinge AB, Atrium Medical Corporation, and Maquet Cardiovascular US Sales, LLC, manufactured and marketed a polypropylene hernia repair mesh that they knew to be dangerous. He alleges that he has suffered permanent injuries from the surgical implantation of such a mesh in his groin. The complaint asserts various product-liability, contract, and tort claims against the defendants, and seeks compensatory and punitive damages.

Defendants have moved to dismiss the complaint on the ground that it fails to state a claim upon which relief can be granted. Getinge and Maquet have also moved to dismiss the claim for lack of personal jurisdiction.

For the following reasons, the motions to dismiss will be granted in part and denied in

part.

A. Factual Background

Unless otherwise noted, the following facts are as set forth in the complaint.

Joseph Paye is a resident of Pennsylvania. (Compl. ¶ 6).

Getinge AB is a Swedish corporation with a principal place of business in Gothenburg, Sweden. Among other things, it researches, develops, tests, manufactures, produces, distributes, markets, promotes, and sells medical devices for hernia repair. (*Id.* ¶ 7).

Atrium Medical Corporation is a Delaware corporation with a principal place of business in New Hampshire. (*Id.* ¶ 8). Atrium is a wholly owned subsidiary of Getinge. (*Id.*).

Maquet Cardiovascular US Sales, LLC is a limited liability company based in New Jersey. (*Id.* ¶ 9). Maquet is also a wholly owned subsidiary of Getinge. (*Id.*).

Getinge, Atrium, and Maquet allegedly control the development, manufacturing, sale, and marketing of ProLoop polypropylene mesh. (*Id.* ¶¶ 7-9). Doctors have used polypropylene mesh in hernia repair surgery since 1958. (*Id.* ¶¶ 14-15). ProLoop is a polypropylene mesh that is intended for repair of inguinal hernias. (*Id.* ¶ 25). Atrium patented the ProLoop mesh in 2004. (*Id.* ¶ 26).

The complaint alleges that polypropylene mesh products in general can cause serious medical complications after implantation. It cites several scientific papers that argue that polypropylene mesh is not biologically inert after implementation, leading to inflammation, foreign-body response, and scar-tissue formation. (*Id.* ¶¶ 16-18). It also cites scientific papers that argue that polypropylene mesh can degrade, crack, and shrink inside the human body, leading to infection, irritation, and serious chronic pain. (*Id.* ¶¶ 19-22).

The complaint further alleges that defendants brought ProLoop to market without obtaining clearance from the Food and Drug Administration. In 1993, Atrium received FDA

premarket clearance for ProLite, a flat, low-profile polypropylene monofilament surgical mesh. (*Id.* ¶ 23). In 2004, Atrium successfully patented ProLoop, a three-dimensional surgical mesh intended to function as a plug, rather than a patch. (*Id.* ¶¶ 24-27). The complaint alleges that the defendants have used the FDA approval obtained for ProLite to market and distribute ProLoop, bypassing the regulatory approval process. (*Id.* ¶¶ 28-30).

Finally, the complaint alleges that ProLoop's design is unreasonably dangerous. It alleges that ProLoop's looped filaments, high volume of non-absorbable synthetic polypropylene, and lack of bridging filaments between mesh loops increase the risk of mesh contracture, meshoma, and inflammatory response. (*Id.* ¶¶ 31-33).[1]

The complaint alleges that on June 12, 2012, Paye underwent inguinal hernia repair surgery at Sturdy Memorial Hospital in Attleboro, Massachusetts. (*Id.* ¶ 38). During the surgery, his doctor implanted a ProLoop mesh into his groin. (*Id.*). Years afterward, his hernia recurred, and he suffered from severe groin pain. (*Id.*). During later surgery, his doctors discovered that the mesh had contracted into a ball, migrated away from the hernia site, and had become surrounded by scar tissue. (*Id.* ¶ 40). His doctors were unable to remove the mesh. (*Id.*). The complaint alleges that the mesh has caused Paye permanent injuries, substantial pain and suffering, emotional distress, medical expenses, lost wages and earning capacity, and diminished quality of life. (*Id.* ¶ 46).

B. Procedural Background

On January 3, 2022, Paye filed a complaint against defendants. He filed an amended complaint on April 30, 2022. The amended complaint asserts seven claims against the

[1] "Meshoma" occurs when surgical mesh shrinks into a ball, possibly trapping nerves and causing inflammation. Kristoffer Andresen & Jacob Rosenberg, *Management of Chronic Pain After Hernia Repair*, 11 J. PAIN RSCH. 675, 676 (2018).

defendants: defective design (Count 1), manufacturing defect (Count 2), failure to warn (Count 3), negligence (Count 4), breach of implied warranty (Count 5), breach of express warranty (Count 6), and negligent misrepresentation (Count 7). The amended complaint seeks compensatory and punitive damages.

Atrium has moved to dismiss the amended complaint under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted.

Getinge and Maquet have moved to dismiss the amended complaint under Fed. R. Civ. P. 12(b)(2) for failure to establish personal jurisdiction and Fed. R. Civ. P. 12(b)(6) for failure to establish a claim upon which relief can be granted.

II. Personal Jurisdiction

Getinge and Maquet contend that the complaint should be dismissed under Fed. R. Civ. P. 12(b)(2) for lack of personal jurisdiction.

A plaintiff bears the burden of establishing that the court has personal jurisdiction over a defendant. *See Daynard v. Ness, Motley, Loadholt, Richardson & Poole, P.A.*, 290 F.3d 42, 50 (1st Cir. 2002). When considering a motion to dismiss under Fed. R. Civ. P. 12(b)(2), the court may use several standards to assess whether a plaintiff has carried that burden: the "*prima facie*" standard, the "preponderance of the evidence" standard, or the "likelihood" standard. *See id.* at 50-51, 51 n.5; *Foster-Miller, Inc. v. Babcock & Wilcox Canada*, 46 F.3d 138, 145-46 (1st Cir. 1995). Where, as here, the court is called to make that assessment without first holding an evidentiary hearing, the *prima facie* standard is applied. *See United States v. Swiss Am. Bank, Ltd.*, 274 F.3d 610, 618 (1st Cir. 2001).

Under that standard, the court takes the plaintiff's "properly documented evidentiary proffers as true and construe[s] them in the light most favorable to [the plaintiff's] jurisdictional claim." *A Corp. v. All Am. Plumbing, Inc.*, 812 F.3d 54, 58 (1st Cir. 2016) (citing *Phillips v.*

Prairie Eye Ctr., 530 F.3d 22, 26 (1st Cir. 2008)). The plaintiff may not "rely on unsupported allegations in its pleadings." *Id.* (quoting *Platten v. HG Bermuda Exempted Ltd.*, 437 F.3d 118, 134 (1st Cir. 2006)) (internal alteration omitted). Instead, the plaintiff "must put forward 'evidence of specific facts' to demonstrate that jurisdiction exists." *Id.* (quoting *Platten*, 437 F.3d at 134). "[T]he plaintiff . . . may rely on jurisdictional facts documented in 'supplemental filings (such as affidavits) [ ] contained in the record.'" *Motus, LLC v. CarData Consultants, Inc.*, 23 F.4th 115, 123 (1st Cir. 2022) (quoting *Baskin-Robbins Franchising LLC v. Alpenrose Dairy, Inc.*, 825 F.3d 28, 34 (1st Cir. 2016)). Facts offered by the defendant "become part of the mix only to the extent that they are uncontradicted." *Astro-Med, Inc. v. Nihon Kohden Am., Inc.*, 591 F.3d 1, 8 (1st Cir. 2009) (quoting *Adelson v. Hananel*, 510 F.3d 43, 48 (1st Cir. 2007)).

The exercise of personal jurisdiction over a defendant must be authorized by statute and consistent with the due-process requirements of the United States Constitution. *See A Corp.*, 812 F.3d at 58 (citing *Daynard*, 290 F.3d at 52). Consistent with those requirements, a court may exercise either general or specific jurisdiction. *See Baskin-Robbins*, 825 F.3d at 35.

> Specific jurisdiction exists when there is a demonstrable nexus between a plaintiff's claims and a defendant's forum-based activities. General jurisdiction exists when the litigation is not directly founded on the defendant's forum-based contacts, but the defendant has nevertheless engaged in continuous and systematic activity, unrelated to the suit, in the forum state.

Swiss Am. Bank, 274 F.3d at 618 (internal citations and quotation marks omitted).

1. General Jurisdiction

As to general jurisdiction, the complaint simply alleges that Getinge is a Swedish corporation doing business in the United States. (Compl. ¶ 7). Plaintiff does not contend that Getinge has "affiliations with [Massachusetts] . . . so 'continuous and systematic' as to render [it] essentially at home." *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011) (quoting *International Shoe Co. v. Washington*, 326 U.S. 310, 317 (1945)). Nor does

plaintiff allege that defendant's affiliations with Massachusetts are so substantial that it is "comparable to a domestic enterprise in that State." *Daimler AG v. Bauman*, 571 U.S. 117, 133 n.11 (2014). Accordingly, the court may not exercise general jurisdiction over Getinge.

Maquet is a Delaware limited liability company whose single member is a New Jersey corporation. (Ex. A ¶ 4, Defs. Reply). Again, the complaint does not allege either that Maquet has continuous and systemic ties to Massachusetts or that its affiliations with Massachusetts are comparable to those of a Massachusetts enterprise. Accordingly, the court may not exercise general jurisdiction over Maquet.

Plaintiff, however, contends in broad terms that the court has general jurisdiction over defendants because they have consented to suit in Massachusetts. Neither the complaint nor plaintiff's opposition to defendants' jurisdictional challenge indicate specifically how Getinge and Maquet have consented to general jurisdiction. Accordingly, plaintiff has not carried his burden to show that the court has general jurisdiction over Getinge and Maquet through their consent.

2. <u>Specific Jurisdiction</u>

As to specific jurisdiction, due process requires that a plaintiff establish three conditions:

> First, the claim underlying the litigation must directly arise out of, or relate to, the defendant's forum-state activities. Second, the defendant's in-state contacts must represent a purposeful availment of the privilege of conducting activities in the forum state, thereby invoking the benefits and protections of that state's laws and making the defendant's involuntary presence before the state's courts foreseeable. Third, the exercise of jurisdiction must be reasonable.

Copia Commc'ns, LLC v. AMResorts, L.P., 812 F.3d 1, 4 (1st Cir. 2016) (quoting *Phillips*, 530 F.3d at 27) (internal alteration omitted); *see also Motus*, 23 F.4th at 122.

Maquet and Getinge contend that plaintiff's claims do not arise out of or relate to their forum-state activities and that they have not purposefully availed themselves of the privilege of

conducting activities in Massachusetts.

a. Maquet

The complaint alleges that Maquet was "involved" in the "research, development, testing, manufacture, production, distribution, marketing, promotion, and/or sale" of ProLoop mesh "at all relevant times hereto." (Compl. ¶ 9). It further alleges that Maquet "is the exclusive distributor of all surgical mesh products manufactured by [d]efendants." (*Id.*). It does not otherwise specify when Maquet's involvement in ProLoop distribution began, or whether it conducted any activities other than distribution. Finally, plaintiff contends (in his opposition, but not the complaint) that Maquet was the "exclusive" distributor of ProLoop mesh after 2011. (Pl. Opp. at 9).

Maquet contends that the claim does not arise out of its forum-state activities because it began distributing ProLoop mesh in 2014, approximately two years after the surgery on plaintiff in which the mesh was implanted. Defendants have provided an affidavit from Atrium's president attesting that Maquet's promotion, sale, and distribution of ProLoop began in January 2014, and that it did not design or manufacture ProLoop mesh products. (Carlton Aff. ¶¶ 16-17). Before 2014, according to the affidavit, Atrium promoted, sold, and distributed ProLoop. (*Id.* ¶ 10).

Plaintiff has not carried his burden to show that his claims arise out of Maquet's contacts with Massachusetts. He has not offered any evidence contradicting defendant's affidavit stating that Maquet only began distributing ProLoop in 2014. Furthermore, the complaint contains no factual allegations from which it could be plausibly inferred that Maquet had any role in the design or manufacture of the product, and again plaintiff has offered no evidence to contradict the statement in the affidavit that it had no such role. Accordingly, plaintiff cannot establish purposeful availment under a "stream of commerce" theory, because Maquet only became

involved in the stream of commerce for ProLoop after his surgery. *See Costa v. FCA US LLC*, 542 F. Supp. 3d 83, 95 (D. Mass. 2021).

It is true that the complaint alleges in general terms that all defendants misrepresented and concealed the dangers of ProLoop mesh for some period of time after the surgery. (Compl. ¶ 45). In some circumstances, manufacturers have a continuing duty to warn customers of dangers from ongoing product use. *Lewis v. Ariens Co.*, 434 Mass. 643, 648-49 (2001). But there are no specific allegations in the complaint concerning the conduct of Maquet after 2014—that is, there are no facts alleged from which it might be plausibly inferred that Maquet (which did not design or manufacture the product) knew or reasonably should have known of the dangers of the product after that point. For purposes of establishing personal jurisdiction, at least, a vague reference that "defendants" concealed the dangers is not enough.

In sum, the complaint does not plead facts sufficient to demonstrate the existence of specific jurisdiction over Maquet, and plaintiff has not submitted evidence to contradict the statements in the affidavit submitted by defendants concerning the activities of Maquet. Accordingly, all counts against Maquet will be dismissed for lack of personal jurisdiction.

b. Getinge AB

The complaint alleges that after Getinge acquired Atrium in 2011, Getinge became involved in the research, marketing, and sale of ProLoop mesh and also controlled Atrium's activities. Getinge contends that Atrium, not it, carried out activities related to ProLoop distribution. It further contends that it did not control Atrium and that therefore the forum contacts of Atrium should not be imputed to it.

Based on the pleadings and supplemental filings, it appears that Getinge did not itself carry out any research, marketing, or sales of ProLoop mesh. The complaint alleges vaguely that Getinge was "involved" with these activities. (Compl. ¶ 7). The only particularized mention of

Getinge's involvement in ProLoop is its alleged application to the FDA for a product name change for ProLoop. (*Id.* ¶ 29). The complaint characterizes that application as an attempt by Getinge to evade regulatory scrutiny of ProLoop mesh. (*Id.*). However, the FDA's response to the application is addressed to an officer at Atrium and does not mention Getinge. And there are no other specific allegations as to the involvement of Getinge in the sale or distribution of the product. Those allegations, without more, are insufficient to establish specific jurisdiction over Getinge.

Plaintiff further contends that Atrium is the *alter ego* of Getinge, and that Atrium's (undisputed) forum contacts should be imputed to it. Ordinarily, courts will treat different corporations as separate entities, even if one wholly owns another. *See Lothrop v. North Am. Air Charter, Inc.*, 95 F. Supp. 3d 90, 99-100 (D. Mass. 2015). A jurisdictional determination that one corporation's forum contacts should be imputed to another requires piercing the corporate veil. *Id.* at 99.

Courts in Massachusetts have applied two approaches in determining whether to pierce the corporate veil. First, some courts have applied the internal-affairs doctrine, which requires courts to apply the substantive law of a corporation's place of incorporation. *See, e.g.*, *Mariasch v. Gillette Co.*, 521 F.3d 68, 71-72 (1st Cir. 2008); *Lily Transp. Corp. v. Royal Inst'l Servs., Inc.*, 64 Mass. App. Ct. 179, 188 n.15 (2005) (applying the law of Pennsylvania to determine whether to pierce a corporate veil). Second, some courts have applied the multifactor test prescribed by the RESTATEMENT (SECOND) OF CONFLICT OF LAWS, § 188 (Am. L. Inst. 1971). *See, e.g.*, *Evans v. Multicon Constr. Corp.*, 30 Mass. App. Ct. 728, 737 n.7 (1991); *John T. Callahan & Sons, Inc. v. Dykeman Elec. Co., Inc.*, 266 F. Supp. 2d 208, 230 (D. Mass. 2003).

The former approach appears to be the more appropriate one for this case. Plaintiff's

contention is that Getinge controlled Atrium's management and operations, and therefore applying the choice-of-law rule that directly addresses such matters is appropriate. *See, e.g.*, *U.S. v. Funds Held in the Name or for the Benefit of Wetterer*, 210 F.3d 96, 106 (2d Cir. 2000) (applying the internal-affairs doctrine to determine which jurisdiction's substantive law should be used for an *alter ego* determination). Application of the internal-affairs doctrine to cases such as this will also provide certainty and predictability to corporate parents whose subsidiaries operate in many jurisdictions. *VantagePoint Venture Partners 1996 v. Examen, Inc.*, 871 A.2d 1108, 1112-13 (Del. 2005).

Atrium is incorporated in Delaware, and therefore the Court will apply Delaware law to determine whether Atrium is an *alter ego* of Getinge.[2] Under Delaware law, piercing the corporate veil requires that the subsidiary be "a sham entity designed to defraud investors and creditors." *Crosse v. BCBSD, Inc.*, 836 A.2d 492, 497 (Del. 2003). A parent entity's ownership of a subsidiary, without more, is insufficient to establish that the subsidiary is an *alter ego*. *CMS Inv. Holdings, LLC v. Castle*, 2015 WL 3894021, at *13 n.27 (Del. Ch. June 23, 2015). "[C]onclusory allegations of domination and control" of the subsidiary by the parents are insufficient. *Wenske v. Blue Bell Creameries, Inc.*, 2018 WL 5994971, at *7 (Del. Ch. Nov. 13, 2018). A parent's ownership of the entirety of a subsidiary's stock and appointment of all of its directors is likewise insufficient. *Id.* Instead, the parent must commit wrongful acts "tied to the manipulation of the corporate form." *Doberstein v. G-P Industries, Inc.*, 2015 WL 6606484, at

[2] While not identical to the Delaware standard, Massachusetts law similarly sets a high bar for piercing the corporate veil. "[E]ven pervasive control [by a parent of a subsidiary], without more, is not a sufficient basis for a court to ignore corporate formalities." *Scott v. NG U.S. 1, Inc.*, 450 Mass. 760, 768 (2008). Ultimately, a "decision to disregard settled expectations accompanying corporate form requires a determination that the parent corporation directed and controlled the subsidiary, and used it for an improper purpose." *Id.* Massachusetts law examines several factors as part of that test, including pervasive control, nonobservance of corporate formalities, misuse of corporate funds, and use of corporate funds for transactions of the dominant corporation. *Id.* The result of the jurisdictional inquiry here would be the same under Massachusetts or Delaware law.

*4 (Del. Ch. Oct. 30, 2015). And "[t]he degree of control required to pierce the veil is exclusive domination and control . . . to the point that the [subsidiary] no longer ha[s] legal or independent significance of [its] own." *Wallace ex rel. Cencom Cable Income Partners II, Inc., L.P. v. Wood*, 752 A.2d 1175, 1184 (Del. Ch. Oct. 12, 1999) (fourth alteration in original) (citations omitted) (quoting *Hart Holding Co. Inc. v. Drexel Burnham Lambert Inc.*, 1992 WL 127567, at *11 (Del. Ch. May 28, 1992).

Plaintiff contends that Getinge assumed control of Atrium's operations after 2011, and that it did business in the United States through Atrium and Maquet. The complaint alleges that Atrium, after becoming a wholly-owned subsidiary of Getinge, ceased filing annual reports with the State of New Hampshire, leading to the suspension of Atrium's authority to do business in that state. (Compl. ¶ 8). Getinge then applied for requalification "using Atrium's corporate name." (*Id.*). The complaint alleges that Getinge now "controls the activities of Atrium and is the direct employer of the individuals formerly employed by Atrium." (*Id.*). Plaintiff has submitted a copy of Getinge's 2011 and 2021 annual reports, both of which describe Atrium as a Getinge subsidiary. (*See* Exs. 1, 2, Pl. Opp.).

According to its president, Atrium maintains its own officers and board of directors and has its own bylaws, corporate records, financial records, payroll, and budgets. (Carlton Aff. ¶ 6, 9, 13). Atrium has always filed applications to for authority to do business under its own name. (*Id.* ¶ 7). Atrium manages and operates its day-to-day business independently of Getinge. (*Id.* ¶ 8). Getinge exercises parental oversight over Atrium, but Atrium has authority to enter most contracts and business agreements without Getinge's approval. (*Id.* ¶ 14). Prior to 2014, Atrium was responsible for marketing, promotion, distribution, and sales of ProLoop mesh. (*Id.* ¶ 10). Atrium's president attests that Getinge has never designed, manufactured, sold, or distributed

ProLoop mesh or any other surgical mesh. (*Id.* ¶ 17-19).

The pleadings and supplemental evidence are insufficient to show that Atrium is an *alter ego* of Getinge. Although Atrium is wholly owned by Getinge, it carries out many activities independently: entering into contracts, applying for business licenses and regulatory approval, paying employees, promoting and distributing products, and managing its day-to-day affairs, all under its own name. Nor is there any evidence that Atrium is a "sham entity" used by Getinge to commit wrongful acts. Neither the complaint nor the proffered evidence suggest that Getinge blatantly disregarded corporate formalities in order to manipulate the corporate form. *Cf. Harco Nat. Ins. Co. v. Green Farms, Inc.*, 1989 WL 110537, at *6 (Del. Ch. Sept. 19, 1989) (suggesting that poor maintenance of corporate records, commingling of assets between shareholders and corporation, and undercapitalization, if shown to be true, may justify piercing the corporate veil).

Under the circumstances, Atrium's forum contacts will not be attributed to Getinge, and the court therefore lacks specific jurisdiction over Getinge. Accordingly, all counts against defendant Getinge will be dismissed for lack of personal jurisdiction.

III. Motion to Dismiss

A. Standard of Review

To survive a motion to dismiss, the complaint must state a claim that is plausible on its face. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In other words, the "[f]actual allegations must be enough to raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556). When determining whether a complaint satisfies that standard, a court must assume the truth of all well-pleaded facts and give

the plaintiff the benefit of all reasonable inferences. *See Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). Dismissal is appropriate if the complaint fails to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008) (quoting *Centro Médico del Turabo, Inc. v. Feliciano de Melecio*, 406 F.3d 1, 6 (1st Cir. 2005)).

B. Analysis

The parties agree that Massachusetts law applies to the substantive claims. Massachusetts courts use a "functional approach" to choice-of-law questions that relies in part on the RESTATEMENT (SECOND) OF CONFLICT OF LAWS (Am. L. Inst. 1971). *Cosme v. Whitin Mach. Works, Inc.*, 417 Mass. 643, 646 (1994). In personal injury cases, Section 146 of the Restatement suggests that the law of the state where the injury occurred should determine the rights and liabilities of the parties unless another state has a more significant relationship to the underlying cause of action. RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 146 (Am. L. Inst. 1971). Massachusetts courts have applied this approach to cases arising from surgical implantation of a medical product such as this one. *Monroe v. Medtronic, Inc.*, 511 F. Supp. 3d 26, 33 (D. Mass. 2021). Plaintiff's surgery took place in Attleboro, Massachusetts. Accordingly, the Court will apply Massachusetts law to his claims.

The complaint styles Counts 1, 2, and 3 as claims of strict liability in tort. Under Massachusetts law, there is no such cause of action. *Swartz v. General Motors Corp.*, 375 Mass. 628, 629 (1978). Instead, in Massachusetts product-liability cases, breach of the implied warranty of merchantability claims are functionally identical to strict-liability claims in other jurisdictions. *See Commonwealth v. Johnson Insulation*, 425 Mass. 650, 653-54 (1997). The Court will therefore construe Counts 1, 2, and 3 as claims for breach of the implied warranty of

merchantability. *See* Fed. R. Civ. P. 8(e). Count 5, in turn, asserts a claim for breach of implied warranty, which is duplicative of those counts as construed here.

To succeed on a claim alleging breach of the implied warranty, the plaintiff must demonstrate (1) that the defendant manufactured or sold the product in question, (2) that a defect or unreasonably dangerous condition existed that rendered the product not suitable for the ordinary uses for which the product was sold, (3) that he was using the product in a manner that the defendant intended or could reasonably have foreseen, and (4) that the defect or unreasonably dangerous condition was a legal cause of his injuries. *AcBel Polytech, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 928 F.3d 110, 116 (1st Cir. 2019). "A product may be defective and unreasonably dangerous because of a manufacturing defect, a design defect, or a warning defect, that is, a failure reasonably to warn of the product's foreseeable risks of harm." *Evans v. Lorillard Tobacco, Co.*, 465 Mass. 411, 422 (2013).

1. Count 1—Strict Liability—Design Defect

For a design-defect claim, a plaintiff must "prove the availability of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff's harm." *Id.* at 428 (quoting RESTATEMENT (THIRD) OR TORTS: PRODUCT LIABILITY § 2 cmt. f (Am. L. Inst. 1998). This inquiry requires the plaintiff to show that "the product in question could have been more safely designed, not that a different product was somehow safer." *Tersigni v. Wyeth*, 817 F.3d 364, 368 (1st Cir. 2016).

The complaint here alleges that ProLoop mesh "deviated from its intended design in that it is unfit for permanent implantation into the human body and fails to provide a permanent repair for hernia." (Compl. ¶ 61). It further alleges that reasonable alternative procedures exist for treating hernias and reasonable alternative designs exist for surgical mesh. (Compl. ¶ 64).

Defendants contend that the design-defect claim should fail because the complaint does

not adequately allege a reasonable alternative design. The complaint alleges, in a single paragraph, that "[f]easible and suitable alternative procedures and instruments, as well as suitable alternative designs for implantation and treatment of hernias and soft tissue repair . . . exist[] . . . as compared to [ProLoop mesh]." (Compl. ¶ 64). It specifically identifies polyvinylidene fluoride mesh, high-density polyethylene mesh, and non-coated, single-layer mesh as examples of feasible alternatives. (*Id.*).

A reasonable alternative design must be a design for the product in question, not a proposal to use a different product altogether. *Tersigni*, 817 F.3d at 368. While there is perhaps some ambiguity in the complaint as to whether the listing of other types of mesh is intended to represent alternative designs or alternative types of treatment or procedure, the complaint specifically alleges that they represent the former. Under the circumstances, the allegations are sufficiently plausible to support a claim of defective design, and dismissal for failure to allege a reasonable alternative is not warranted. Whether discovery may reveal a different set of facts is a question for another day.

In short, the complaint alleges sufficient facts to support a breach of warranty claim based on a design defect. Accordingly, the motions to dismiss will be denied as to Count 1.

2. Count 2—Strict Liability—Manufacturing Defect

The complaint alleges that the ProLoop mesh used in plaintiff's surgery did "not conform to [the] manufacturer's expectations in that, *inter alia*, it is not safe for implantation in the human body." (Compl. ¶ 70). The complaint further alleges that the mesh "failed to incorporate and migrated." (*Id.*).

A manufacturing defect may cause a product to be defective or unreasonably dangerous. *Evans*, 465 Mass. at 422. In a manufacturing-defect case, the factfinder must "compare the propensities of the product as sold with those which the product's designer intended it to have"

and determine "whether the deviation from the design rendered the product unreasonably dangerous and therefore unfit for its ordinary purposes." *Back v. Wickes Corp.*, 375 Mass. 633, 641 (1978).

Here, the complaint fails to allege a plausible basis to conclude that the ProLoop mesh deviated from its intended design. It alleges that ProLoop mesh contains "a number of *design* elements which render the product unreasonably dangerous," including looped filaments, lack of bridging filaments, and high volume of non-absorbable synthetic polypropylene material. (Compl. ¶ 32 (emphasis added)). As the complaint makes clear, those allegedly harmful elements are part of the product's design. Their use was not a deviation from the manufacturer's design; it was entirely consistent with the design. The complaint further alleges that Atrium knew that "its chosen polypropylene lacked anti-oxidants" when it elected to begin production of ProLoop mesh, increasing the risk of complications after implantation. (Compl. ¶¶ 33-37). Plaintiff characterizes this feature as a deviation from the design because the defendants "performed [their] own tests demonstrating the faster degradation of said material." (Pl. Opp. at 9). But that allegation describes a deliberate decision to include a particular feature in a product line. If true, that is a design defect, not a manufacturing defect.

The complaint therefore fails to allege that the product as manufactured deviated from the manufacturer's intended design, and accordingly Count 2 will be dismissed.

3. Count 3— Strict Liability—Failure to Warn

Count 3 alleges that defendants failed to warn plaintiff and his treating physician about the risks associated with ProLoop mesh, its inadequate research and testing of ProLoop mesh, and the lack of a safe and effective removal procedure. It also alleges that defendants did not inform plaintiff's treating physician of the proper technique and methods of implantation and patient selection. Finally, it alleges that defendants concealed information about the risks from

defendant and his treating physician.

"A manufacturer of a product has a duty to warn foreseeable users of dangers in the use of that product of which he knows or should have known." *Mitchell v. Sky Climber, Inc.*, 396 Mass. 629, 631 (1986). A manufacturer may be held liable "even if the product does exactly what it is supposed to do, if it does not warn of the potential dangers inherent in the way a product is designed." *Laaperi v. Sears, Roebuck & Co.*, 787 F.2d 726, 729 (1st Cir. 1986). "It is not necessary that the product be negligently designed or manufactured." *Id.*

Under the "learned intermediary" doctrine, a medical-device manufacturer's obligation to warn of dangers associated with its product runs to the physician, not the patient. *Cottam v. CVS Pharm.*, 436 Mass. 316, 321 (2002); *Langlois v. American Med. Sys., Inc.*, 462 F. Supp. 3d 1, 4 (D. Mass. 2020). A plaintiff "carries the initial burden of producing sufficient evidence that the defendant manufacturer failed to warn of a non-obvious risk about which the manufacturer knew or should have known." *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 81 (1st Cir. 1992). Factors relevant to determining the adequacy of a warning include

> whether the warning adequately indicates the scope of the danger; whether the warning reasonably communicates the extent or seriousness of the harm that could result from misuse of the product; whether the physical aspects of the warning adequately alert a reasonably prudent person to the danger; and whether the means to convey the warning are adequate in the given circumstances.

Albright v. Boston Sci. Corp., 90 Mass. App. Ct. 213, 220 n.17 (2016) (quoting *In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 812 (N.D. Ohio 2004).

Defendants contend that the failure-to-warn claim is too conclusory to survive a motion to dismiss. It is true that a central question in failure-to-warn cases is a comparison of the actual warning (if any) given by the manufacturer with the proposed warning that plaintiff says should have been given. *See, e.g., Niedner v. Ortho-McNeil Pharm., Inc.*, 90 Mass. App. Ct. 306, 309–10 (2016); *Kalivas v. A.J. Felz Co.*, 15 Mass. App. Ct. 482, 487 (1983); *Penn-America Ins. Co. v.*

Bay State Gas Co., 96 Mass. App. Ct. 757, 761–62 (2019); *KomTek v. Tucker & Rice, Inc.*, 1993 WL 818821, at *3-4 (Mass. Super. Ct. Dec. 22, 1993). When a complaint simply recites the elements of a failure-to-warn claim in boilerplate language without providing specific details about a defendant's omissions or inadequacies, normally the plaintiff has failed to carry his burden to show a failure to warn. *See, e.g.*, *Bustamante v. Atrium Med. Corp.*, 2020 WL 583745, at *7 (S.D.N.Y. Feb. 6, 2020) (dismissing a failure-to-warn claim because "[n]otably absent from Plaintiffs' Amended Complaint is the exact language of the warnings contained on the device"); *Nowell v. Medtronic Inc.*, 372 F. Supp. 3d 1166, 1251-1255 (D.N.M. 2019) ("[Plaintiff] has not alleged that the Defendants sold their mesh absent any warning, and the Court will not presume this fact on [plaintiff's] behalf."); *Bond v. Johnson & Johnson*, 2021 WL 6050178, at *11 (D.N.J. Dec. 21, 2021) ("[Plaintiff] has not alleged the specific language in the warnings associated with the Prolene 3D . . . the Court is unable to assess the warnings against the omissions [plaintiff] alleges.").

Here, the complaint alleges that defendants "failed to properly and adequately warn" plaintiff and his physician of various risks associated with ProLoop. (Compl. ¶¶ 74-76). Paragraphs 32 through 54 allege in some detail that defendants failed to warn plaintiff and his physician of a variety of allegedly unsafe characteristics. While the complaint does not specifically allege what warning was given as to those dangers, it does allege that defendants "made a deliberate decision to ignore" them. (*Id.* ¶ 37). The complaint may be plausibly read to allege that defendant gave no warning at all about those identified dangers, and that defendant should have provided such a warning.

Under the circumstances, the complaint alleges sufficient facts to sustain a claim for breach of warranty based on failure to warn, and the motion to dismiss as to Count 3 will be

denied.

4. Count 4—Negligence

Count 4 alleges that defendants were negligent in (1) designing ProLoop mesh, (2) failing to warn plaintiff and his treating physicians of risks associated with ProLoop mesh, (3) failing to comply with state and federal regulations concerning ProLoop mesh, and (4) manufacturing and bringing ProLoop mesh to market despite its alleged dangers.[3]

Count 4 does not allege one specific theory of negligence. Rather, the claims sound in negligent design, negligent manufacture, and negligent failure to warn. Under Massachusetts law, "[i]n most substantive aspects . . . the negligence and warranty inquiries are congruent." *Gillispie v. Sears, Roebuck & Co.*, 386 F.3d 21, 26 (1st Cir. 2004). Here, they are entirely congruent. Count 4 is therefore entirely duplicative of Counts 1, 2, and 3, and will be dismissed on that basis.

5. Count 5—Breach of Implied Warranty

Count 5 alleges that defendants breached the implied warranty that the ProLoop mesh implanted in plaintiff was "of merchantable quality" and "safe and fit for the [sic] use in hernia repair." Count 5 is likewise duplicative and will be dismissed.

6. Count 6—Breach of Express Warranty

The complaint alleges that defendants expressly represented to plaintiff and his treating physicians that that ProLoop mesh was safe and effective. The complaint alleges that these statements were "made by [d]efendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials." (Compl. ¶ 99).

[3] Plaintiff argues that defendants have not moved to dismiss Count 4. (Pl. Opp. at 5). However, Atrium's motion to dismiss, which Getinge and Maquet have adopted, makes clear that Atrium moves to dismiss the entire complaint, applying the same reasoning to plaintiff's negligence claims as with plaintiff's strict-liability claims. (Atrium Mem. at 7).

Under Massachusetts law, an express warranty can be created in three ways:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the sample or model.

Mass. Gen. Laws ch. 106, § 14.

Defendant contends that the allegations in the complaint are too conclusory to sustain a claim for breach of express warranty claim. Courts evaluating express warranty claims must look to the specific affirmations or promises made by a defendant. *See, e.g.*, *Niedner*, 90 Mass. App. Ct. at 313. If a plaintiff has not identified a specific affirmation or promise, then a factfinder cannot evaluate whether the affirmation or promise relates to the goods, whether the affirmation or promise is part of the basis of the bargain, or whether the goods conform to the affirmation or promise. *See Taupier*, 490 F. Supp. 3d at 438.

Here, the complaint does not identify any specific express affirmation or promise. It does allege that the defendants "expressly represented and warranted . . . orally and in publications, package inserts and other written materials intended for physicians, healthcare providers, medical patients and the general public, that ProLoop polypropylene mesh is safe, effective, fit and proper for its intended use in hernia repair." (Compl. ¶ 99). Under other circumstances, that might well be inadequate to state a claim. However, given the comprehensive regulation of medical devices, including regulation of package inserts and other forms of labeling, the court will permit the claim to proceed to the extent it relies upon written representations set forth in such labeling materials. The claim of express warranty based on oral communications will,

however, be dismissed for failure to identify the alleged express affirmation or promise upon which that claim relies.

7. Count 7—Negligent Misrepresentation

Count 7 alleges that defendants misrepresented that ProLoop mesh was safe, fit, and effective to plaintiff, his treating physicians, and the public. It alleges that defendants conducted "a sales and marketing campaign" to promote ProLoop mesh and "willfully deceive" plaintiff, his treating physicians, and the public about the dangers and consequences of ProLoop mesh. It further alleges that defendants themselves, their sales representatives, and other authorized agents made these misrepresentations in "publications and other written materials." According to the complaint, defendants "made the foregoing representations without any reasonable ground for believing them to be true."

Under Massachusetts law, a negligent misrepresentation requires the plaintiff to show that the defendant

> (1) in the course of his business, (2) supplie[d] false information for the guidance of others (3) in their business transactions, (4) causing and resulting in pecuniary loss to those others (5) by their justifiable reliance upon the information, and (6) with failure to exercise reasonable care or competence in obtaining or communicating the information.

Nota Constr. Corp. v. Keyes Assocs., Inc., 45 Mass. App. Ct. 15, 19-20 (1998).

Defendants contend that the complaint should be held to the heightened pleading standard of Rule 9(b), which requires that a party alleging fraud or mistake "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "In such cases, the pleader usually is expected to specify the who, what, where, and when of the allegedly false or fraudulent representation." *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004). The First Circuit has held that Rule 9(b) should be read "expansively to cover associated claims where the core allegations effectively charge fraud." *North Am. Cath. Educ.*

Prog. Found., Inc. v. Cardinale, 567 F.3d 8, 15 (1st Cir. 2009). "[M]isrepresentation is considered a species of fraud." *Alternative Sys. Concepts, Inc.*, 374 F.3d at 29. Courts in this district are split on whether Rule 9(b)'s heightened pleading standard should always apply to negligent misrepresentation claims. *Gardner v. Simpson Fin. Ltd. P'Ship*, 2012 WL 1109104, at *4 n.12 (D. Mass. Mar. 30, 2012) (highlighting split opinions). In the Court's view, application of Rule 9(b)'s heightened pleading standard is appropriate where "the claims overall sound in fraud." *Miller Inv. Tr. v. Morgan Stanley & Co., LLC*, 308 F. Supp. 3d 411, 449 (D. Mass. 2018). "The hallmarks of fraud are misrepresentation or deceit." *Ed Peters Jewelry Co., Inc. v. C & J Jewelry Co., Inc.*, 215 F.3d 182, 191 (1st Cir. 2000).

The complaint alleges a campaign by the defendants to deceive patients, doctors, and the public about the risks of ProLoop mesh in order to increase sales. The complaint alleges that defendants "made misrepresentations" and "willfully deceived" "without any reasonable ground for believing [their representations about ProLoop] to be true." (Compl. ¶ 103). Those allegations clearly invoke misrepresentation and deceit by defendants, and therefore Count 7 sounds in fraud and must be pleaded according to the standard of Rule 9(b). The complaint does not describe the "who, what, where, and when of the allegedly false or fraudulent representation." *Alternative Sys. Concepts, Inc.*, 374 F.3d at 29. It suggests that these misrepresentations were made by "sales representatives," "authorized agents," "publications," and "written materials," but these descriptors do not state the perpetrators or circumstances of fraud with particularity. The complaint does not identify any particular location where plaintiff or his physicians were misled. Nor does the complaint provide any temporal particularity; it alleges that the misrepresentations were made "[a]t all times herein mentioned." (Compl. ¶ 103). Accordingly, Count 7 is a "barebones" claim that cannot survive Rule 9(b)'s heightened pleading

standard. *Alternative Sys. Concepts, Inc.*, 374 F.3d at 29.

8. Punitive Damages

Plaintiff contends that defendant's conduct is so "despicable" and "contemptible" that he is entitled to punitive damages. (Compl. ¶ 124).

Under Massachusetts law, punitive damages are not permitted "unless expressly authorized by statute." *Flesner v. Technical Commc'ns Corp.*, 410 Mass. 805, 813 (1991). Plaintiff has not identified any Massachusetts statute that would authorize punitive damages for the alleged conduct. Accordingly, the Court will dismiss the claim for punitive damages.

IV. Conclusion

For the foregoing reasons,

1. Counts 1, 2, and 3 are construed as claims for breach of implied warranty under Massachusetts law.
2. The motion to dismiss of defendant Atrium Medical Corporation is GRANTED as to Counts 2, 4, 5, and 7; as to Count 6 to the extent it alleges oral representations; and as to the claim for punitive damages, and otherwise DENIED.
3. The motion to dismiss of defendants Getinge AB and Maquet Cardiovascular US Sales, LLC is GRANTED as to lack of personal jurisdiction, and otherwise DENIED as moot.

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
Chief Judge, United States District Court

Dated: January 19, 2023